

Appl. No. : **10/779,412**
Filed : **February 13, 2004**

REMARKS

Applicants have amended claims 1, 13, 33, and 34. Claim 12 is cancelled without prejudice to, or disclaimer of, the subject matter contained therein. Applicants reserve the right to pursue the subject matter of claim 12 in this or any other patent application. No new claim is added. Accordingly, claims 1, 7-10, 13-24, and 27-37 remain pending, of which claims 7, 8, 16, 19-21, 23-24, and 29 are withdrawn.

Applicants have considered all of the Examiner's objections and rejections set forth in the Final Office Action of July 8, 2011 and respond fully below.

Rejections under 35 U.S.C. § 112, First Paragraph, and 35 U.S.C. § 101

Claim 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-37 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being supported by an enabling disclosure. The claims are also rejected under 35 U.S.C. § 101 under a parallel reasoning. Applicants respectfully traverse.

Specific Binding with Target Polynucleotide

The Examiner alleges that the conditions of claims 1 and 33 can encompass conditions where non-specific binding can occur. Claims 1 and 33 as amended herewith encompasses conditions where the sensor PBP specifically binds to the target polynucleotide. Support for this amendment is found throughout the specification, for example in the discussion beginning on page 11, line 19 of the specification as filed (Paragraph [0044] *et seq.* of the published application).

Specific Binding with Conjugated Polymer

The Examiner alleges that because claim 12 encompasses embodiments where the presence of organic solvents is contemplated to reduce the hydrophobic interactions between the sensor PBP and the conjugated polymer, then "claim 1 must encompass conditions where no 'sufficient amount of an organic solvent' is used ... [and] hydrophobic interactions between the sensor PBP and the (non-specifically formed) 'conjugated polymer' can proceed at will."

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Applicants respectfully submit that the Examiner's interpretation is incorrect. The examples in the specification show that when the sensor PBP and the conjugated polymer are mixed together without the specifically targeted polynucleotide, there is little to no signal generated. For example, in Figures 6-9 there is no detectable signal at 525 nm for when there is no specific recognition of the target polynucleotide. This shows that, contrary to the Examiner's characterization of a hypothetical situation, in practice there is no hydrophobic interaction "proceed[ing] at will." Even in potential situations where some hydrophobic interaction between the sensor PBP and the conjugated polymer is observed, the extent of the interaction would be small such that any generated signal would be treated as noise and subtracted from the spectrum as is commonly done by those skilled in the art using negative controls. This is practical since the height of that background noise would be significantly smaller than the signal generated when there is a target polynucleotide present.

Preamble

Applicants have amended the preamble of the claims to better capture the purpose of the assay method. The assay is conducted to determine whether a target polynucleotide is present in the test sample or not. The preamble and the last clause of claims 1 and 33 are amended accordingly.

In view of these amendments, Applicants respectfully submit that rejections under both 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 101 are overcome. Applicants respectfully request that the Examiner reconsider and withdraw these rejections.

Rejections under 35 U.S.C. § 112, Second Paragraph

"Conjugated polymer"

The Examiner alleges that the metes and bounds of "conjugated polymer" cannot be determined. Applicants respectfully traverse. It is axiomatic in patent law that an applicant need not disclose or explain that which is well-known in the art. The term "conjugated polymer" is used extensively in the art and is quite well-recognized. The specification cites, and Applicants have provided the Office with, references by McQuade et al. and Chen et al. (references 24 and

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25, cited on page 20, line 6 (Paragraph [0071] of the published application)), which refer to “conjugated polymers,” indicating that this term is well-used and well-understood in the art.

Analysis Step

As discussed above, the claims have been amended to read on a process of determining the presence of a target polynucleotide. Applicants respectfully submit that in view of the claim amendments the rejection directed to omitting an essential step is now moot.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Applicants have submitted herewith \$930 for a Request for Continued Examination and \$1,270 for a three-month extension of time, extending the period for response to Monday January 9, 2012. Applicants invite the Examiner to call the undersigned if any issue can be resolved through a telephonic discussion.

Respectfully submitted,
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